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10/780,444	02/17/2004	Peter M. Bonutti	782-A03-023	2789
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PAUL D. BIANCO			SZPIRA, JULIE ANN	
Fleit Gibbons Gutman Bongini & Bianco PL			ART UNIT	PAPER NUMBER
21355 EAST DIXIE HIGHWAY				3731
SUITE 115				
MIAMI, FL 33180				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/780,444	BONUTTI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	JULIE A. SZPIRA	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 December 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6,8-24 and 49-73 is/are pending in the application.  
 4a) Of the above claim(s) 9-17 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-6,8,18-24 and 49-73 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/4/2009 12/4/2009 12/4/2009 12/4/2009</u> | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

Receipt is acknowledged of applicant's amendment filed 12/4/2009.

Claims 1-6, 8-24 and 49-73 are pending and an action on the merits is as follows.

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 63 and 69 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 63 and 69 recite the limitation "the object". There is insufficient antecedent basis for this limitation in the claim. Since "an object" is recited in the preamble as an intended use limitation (i.e. the fastener is intended to be used to secure an object), it is not positively claimed as a structural element.

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

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1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. **Claims 1-8, 19, 24 and 50-62, 64, 65, 67, 68 and 70-73,** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt (US 5,208,950)** in view of **Pontaoe (US 6,618,910).**

**Regarding claim 1,** Merritt discloses a device that is capable being implanted and securing an object relative to a body tissue (cord lock, 10) comprising a first (male body, 14) section including a first surface (54) and an extension member (projection, 66) extending from that surface, and a second (female body, 12) section including a second surface (34) opposing the first surface and being configured for receiving the extension member (recess, 35), the first and second section being bondable together with the application of an energy source (ultrasonic welding; column 4, lines 35-36), but fails to disclose wherein the object extends through the fastener substantially unobstructed.

However Pontaoe teaches a device capable of retaining a suture that allows the object to extend through the object substantially unobstructed (column 3, lines 34-41). There is an embodiment wherein the passageways are disclosed as being devoid of teeth or constricted portions, thus allowing the object to extend through the device unhampered.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to allow the object to pass through the fastened substantially unobstructed to prevent unnecessary pulling force to be applied to the suture during

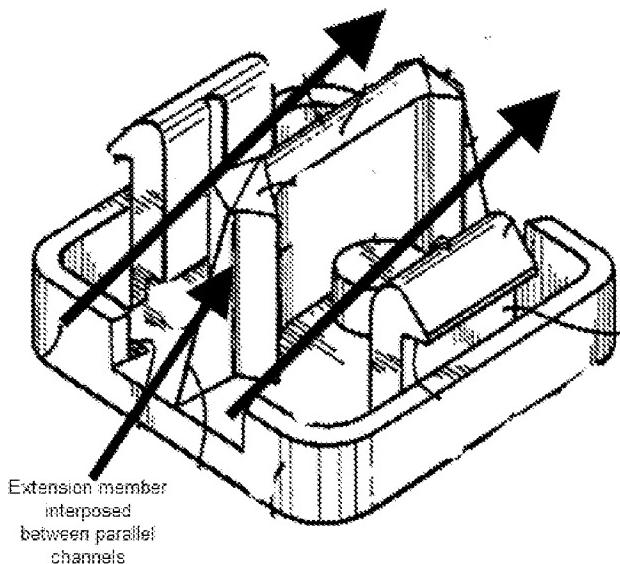
adjustment, as well as to prevent frictional stress on the suture which may cause fraying that would weaken the suture. The passageways extend completely through the body portion to allow for cord (suture) portions to be retained therein (column 2, lines 48-54).

**Regarding claim 2**, Merritt discloses an object (cord) interposed between the first and second sections (column 3, lines 15-18).

**Regarding claim 3**, Merritt discloses the first and second section bonded (snap-locked) together to secure the object (column 4, lines 13-20).

**Regarding claim 4**, Merritt discloses the first section including a pair of parallel channels (Figure 4, see below) for carrying a first portion of the object in a first of the pair of parallel channels and for carrying a second portion of the object in a second of the pair of the parallel channels.

### Parallel Channels



**Regarding claim 5**, Merritt discloses the extension member (66) interposed between the pair of parallel channels (Figure 4, see above).

**Regarding claim 6**, Merritt discloses the second section including a channel (recess, 35) configured for receiving the extension member (column 3, lines 56-59).

**Regarding claim 7**, Merritt discloses the object (cord) including a first (19) and second (21) end, one each positionable within the parallel channels (column 3, lines 62-64; Figure 1).

**Regarding claim 8**, Merritt discloses the suture interposed between the first and second sections when the extension member is positioned within the channel (column 4, lines 16-20).

**Regarding claim 19**, Merritt discloses the first and second sections interconnected by a system of pins and recesses (column 4, lines 11-16).

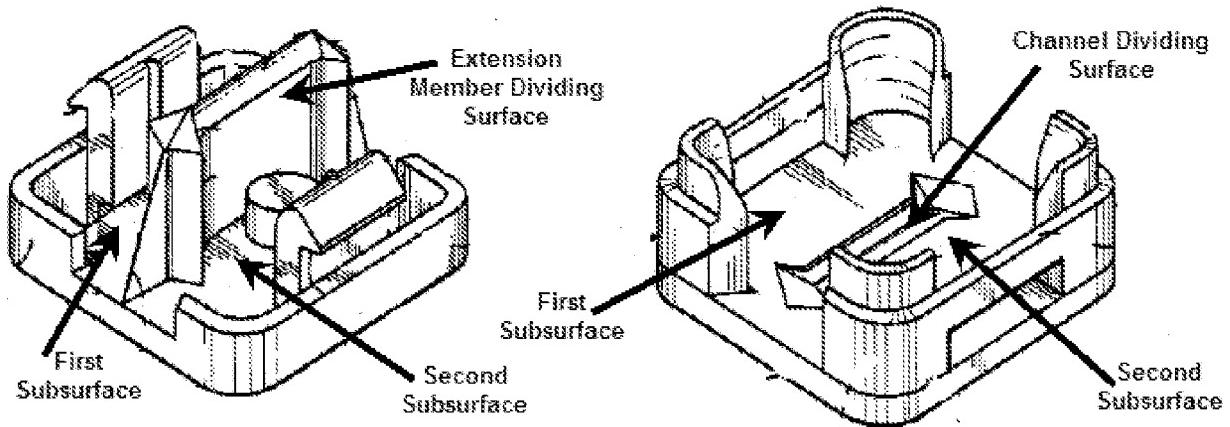
**Regarding claim 24**, Merritt discloses the energy source being ultrasonic energy (welding) (column 4, lines 33-36).

**Regarding claim 50**, Merritt discloses the first section has two channels (76) formed therein, said channels being disposed opposingly about and immediately adjacent to said extension member and the second section is configured to seat within the channels of the first section (Figure 3).

**Regarding claim 51**, Merritt discloses said extension member divides said first surface into a first first-surface subsurface and a second first-surface subsurface, a channel divides said second surface into a first second-surface subsurface and a second - surface subsurface (See Figure Below), said first first-surface subsurface is configured to align with said first second-surface subsurface when said first section is bonded to said second section; and said second first-surface subsurface is configured

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to align with said second second-surface subsurface when said first section is bonded to said second section (Figure 3)



**Regarding claims 52 and 54,** Merritt discloses an object (cord) sandwiched between a first first-surface subspace and said first second-surface subspace and a second first-surface subspace and said second second-surface subspace (Figure 1).

**Regarding claim 53,** Merritt discloses the object being elongated (cord, 10; Figure 1).

**Regarding claims 55-57,** Merritt in view of Pontaoe discloses the invention substantially as claimed above, but fails to disclose the object being body tissue or metallic.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the object body tissue or metallic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Furthermore, the device as claimed is capable of securing a variety of material and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).

**Regarding claim 58-60, 62, 64, 65, 67 and 70-73**, Merritt in view of Pontaoe discloses the invention substantially as claimed above, and Merritt further discloses said extension member bonded to the second surface and is compressible during the application of the energy source to move said first surface and said second surface closer to each other and is compressible with the application of the energy source to a height about equal to a thickness of the object to be secured, the fastener is rigid when the energy source is not being applied, and has a top surface configured to contact the energy source and a bottom surface configured to contact an anvil.

The extension member is deformable as it is made to glass filled nylon, thus allowing for the extension member to be strong and rigid with and application of force and deformed (or compressed) with the application of mechanical energy in the form of pressure to push two sections together. The extension member is bonded to the second section through frictional engagement, and thus meets the limitations of the claims.

**Regarding claim 61**, Merritt discloses the fastener is made of a biocompatible material (glass-filled nylon). Glass-filled nylon is a biocompatible material well known in

the art as shown in paragraph [0084] of external reference patent Anderson et al. (US 2002/0183762).

**Regarding claim 68,** Merritt discloses the extension member is fin shaped (wherein "fin" is taken to mean "a standing ridge located on an object").

**Regarding claims 63 and 69,** Merritt in view of Pontaoe discloses the invention substantially as claimed above, but fails to disclose the object being rigid or metallic.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the object rigid or metallic, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Furthermore, the device as claimed is capable of securing a variety of material and it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).

7. **Claim 20** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt (US 5,208,950)** in view of **Pontaoe (US 6,618,910)** further in view of **Hart (US 5,630,824)**.

**Regarding claim 20,** Merritt in view of Pontaoe discloses the invention substantially as claimed above, but fails to disclose the suture retainer made of a biodegradable material.

However, Hart teaches a suture retainer (attachment device) made of a biodegradable polymer (column 4, lines 50-52).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the suture holder out of a biodegradable material so the device can dissolve after the wound which the suture is attached to heals (column 4, lines 52-65).

8. **Claim 21** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt (US 5,208,950)** in view of **Pontaoe (US 6,618,910)** further in view of **Tokushige et al. (US 5,866,634)**

**Regarding claim 21**, Merritt in view of Pontaoe discloses the invention substantially as claimed above, but fails to disclose the suture retainer made of heat shrink material.

However, Tokushige et al. teaches a biodegradable shrink material that has superior strength, flexibility, and the ability to shrink at lower temperatures (column 1, lines 39-42; column 4, lines 19-22).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the suture holder out of a heat shrink material because it would allow the suture retainer to shrink around the suture (container) with minimal warping (column 3, lines 24-26).

The “lower temperature” that affects the shrink material that is disclosed by Tokushige is advantageous for a device intended to be used within or near a human body as the device will have the physical properties that are desirable with heating,

but not need a tremendous temperature change for the change to occur. This is prevent accidental singeing or burning of a patient during the application of heat, as the heat will not be required to be tremendously high.

9. **Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merritt (US 5,208,950) in view of Pontaoe (US 6,618,910) further in view of Bartlett (US 5,879,372).**

**Regarding claim 22,** Merritt in view of Pontaoe discloses the invention substantially as claimed above, but fails to disclose the suture retainer including viable cells.

However, Bartlett teaches the suture retainer (anchor) including viable cells (bone tissue) (column 4, lines 34-36 and 46-50).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include viable cells to strengthen the area in which the device is placed (column 4, lines 24-26).

10. **Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Merritt (US 5,208,950) in view of Pontaoe (US 6,618,910) further in view of Rhee et al. (US 5,752,974).**

**Regarding claim 23,** Merritt in view of Pontaoe discloses the invention substantially as claimed above, but fails to disclose the suture retainer including a pharmaceutical agent, wherein that agent is osteoinductive

However, Rhee et al. teaches the closure material containing a pharmaceutical agent that is osteoinductive (causes cell growth) such as a growth factor (column 6, line 58-column 7, line 23).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to include a pharmaceutical agent to exert biological effects in vivo, such as the promotion of cell growth (column 6, lines 58-62).

11. **Claim 64** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Merritt (US 5,208,950)** in view of **Pontaoe (US 6,618,910)** further in view of **Egan (US 6,174,324)**.

**Regarding claim 64**, Merritt in view of Pontaoe discloses the invention substantially as claimed above, but fails to disclose the energy source being an ultrasonic end effector.

However, Egan et al. discloses the energy source being an ultrasonic end effector (110).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to use an ultrasonic end effector as an energy source to form a bond between the suture strands and the fastener in the area to which ultrasonic energy is applied, in order to allow the fastener to retain the suture strands therein (column 6, lines 14-18)

#### ***Response to Arguments***

12. Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

13. In this case, the device disclosed by Merritt is structurally similar to many suture anchors well known in the art. The application of a cord retainer as a suture retainer is well within the knowledge of one having ordinary skill in the art. The decision to make the device disclosed by Merritt from a variety of different materials suitable for a suture anchor, such as a biodegradable material or a heat shrink material would have been obvious to one having ordinary skill in the art.

The intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. The devices disclosed by Merritt and Egan have the capability of performing the intended use. The current claims do not positively recite the fastener being implanted in a body, and only claims "an implantable fastener" meaning that any place of implantation (within an elastic netting, in a machine or any other place) that places the fastener relative to the body would meet the claim. The term "relative" also has a very open meaning. As long as a relative term (i.e. near, far, left, right, up, down) is used to describe the relationship of the fastener to the body, the claim limitations are met.

The argument that Merritt does not disclose the first and second sections being ultrasonically welded together is not persuasive. Merritt discloses the first and second sections can be snap-locked together (column 2, lines 64-68), and then later discloses that other means, such as ultrasonic welding could be used. The disclosure of the joining of the sections of Merritt is distinct enough to convey that the first and second

sections of the fastener are to be joined together, thus meeting the limitations of the claims as currently written.

Regarding the argument that the first and second sections are not bonded by the application of ultrasonic energy by Egan, the bonding of the first and second sections occurs through the bonding of the suture strands to the first and second sections. When the suture is bonded to both the first and second sections, the first and second sections are bonded together due to the adhesion created by the suture strand.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIE A. SZPIRA whose telephone number is (571)

270-3866. The examiner can normally be reached on Monday-Thursday 9 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. A. S./  
Examiner, Art Unit 3731  
March 23, 2010

/Gary Jackson/  
Supervisory Patent Trainer  
TC 3700  
March 28, 2010